UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD FROEHLICH, on behalf of himself and all others similarly situated, Plaintiff, v. SANOFI-AVENTIS U.S. LLC, SANOFI US SERVICES INC., CHATTEM, INC., BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and WALMART INC., Defendants.	Civil Action No.: **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Richard Froehlich Swearingen ("Plaintiff") brings this action on behalf of himself and all others similarly situated against Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. (collectively "Sanofi"), Chattem, Inc. ("Chattem"), Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), and Walmart Inc. ("Walmart") (collectively, "Defendants"). Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge.

NATURE OF THE ACTION

1. This is a class action lawsuit regarding Defendants Sanofi and Boehringer's manufacturing and Defendant Chattem's distribution of Zantac, an over-the-counter medication that contain dangerously high levels of N-nitrosodimethylamine ("NDMA"), a carcinogenic and liver-damaging impurity. Additionally, Defendant Walmart sold the defective medication to Plaintiff and other similarly situated consumers.

2. Zantac, an over-the-counter medication that contains the drug ranitidine, decreases

the amount of acid created by the stomach. Over-the-counter Zantac is used for the treatment of heartburn associated with acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease.[1] Zantac was the first drug to surpass $1 billion in sales,[2] and as recently as 2018, Zantac was widely used and remained one of the most popular tablet brands of antacid in the United States, with sales of Zantac 150 (the over-the-counter tablets containing a 150 mg dose) totaling $128.9 million annually,[3] largely because it was marketed as safe.[4] These record sales have only been made possible by the manufacturers, distributers and retailers concealing defects in the design and manufacture of Zantac.

3. Sanofi has owned the U.S. rights to over-the-counter Zantac since approximately January 2017, and has manufactured and distributed the drug during that period. Previously, Defendant Boehringer owned the U.S. rights to over-the-counter Zantac and manufactured and distributed the drug from approximately October 2006 to January 2017.

4. Neither the manufacturers, distributors nor retailers ever disclosed to consumers that the drug has two critical defects: First, ranitidine, the active ingredient in Zantac, is an inherently unstable compound, which as manufactured, stored, shipped and stored causes Zantac to contain dangerously high levels of NDMA; and second, when ingested, Zantac produces in the human body even higher quantities of NDMA.

5. NDMA is a semi-volatile organic chemical, produced as by-product of several

[1] *Ranitidine hydrochloride – Drug Summary*, PRESCRIBER'S DIGITAL REFERENCE (last visited Dec. 03, 2019), https://www.pdr.net/drug-summary/Zantac-150-and-300-Tablets-ranitidine-hydrochloride-241

[2] Richard Wright, *How Zantac Became the Best-Selling Drug in History*, 16 J. OF HEALTHCARE MARKETING 24, 27 (1996).

[3] See, e.g., *Leading antacid tablet brands in the United States in 2018, based on sales, STATISTA* (last visited Dec. 3, 2019), https://www.statista.com/statistics/194544/leading-us-antacid-tablet-brands-in-2013-based-on- sales/.

[4] *Id*. at 27.

industrial processes. According to the U.S. Environmental Protection Agency, NDMA "is a member of N-nitrosamines, a family of potent carcinogens," – a chemical that the World Health Organization has described as "clearly carcinogenic."[5] While NDMA is not currently produced in the United States other than for research purposes, it was formerly used "in production of liquid rocket fuel," among other uses. NDMA is listed as a "priority toxic pollutant" in federal regulations. *See* 40 CFR § 131.36. Exposure to NDMA can cause liver damage and cancer in humans. NDMA is classified as a probable human carcinogen, and animal studies have shown that exposure to NDMA has caused tumors primarily of the liver, respiratory tract, kidney and blood vessels. The carcinogenic nature of NDMA has been publicly known for over 40 years.[6]

6. Recent scientific testing conducted by Valisure LLC and ValisureRX LLC (collectively "Valisure") "has detected extremely high levels of NDMA in all lots [of ranitidine] tested, across multiple manufacturers of ranitidine products," including Zantac.[7]

7. Valisure's gas FDA approved chromatography/mass spectrometry ("GC/MS") testing protocol has detected 2,511,469 ng of NDMA per 150 mg tablet of Zantac.[8] In other words, the FDA protocol detects a quantity of NDMA in each Zantac tablet that is more than 26,000 times

[5] R.G. Liteplo, et al., *Concise International Chemical Assessment Document 38: N-Nitrosodimethylamine*, WORLD HEALTH ORGANIZATION (2002), available at https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf.

[6] See, e.g., Jane Brody, *Bottoms Up: Alcohol in moderation can extend life*, THE GLOBE AND MAIL (CANADA) (Oct. 11, 1979) ("As one of a family of carcinogens called nitrosamines, NDMA has caused cancer in nearly every laboratory animal tested so far.").

[7] Valisure Citizen Petition to FDA ("Valisure Petition") at 6 (emphasis added), available at https://hbw.pharmaintelligence.informa.com/~/media/Supporting%20Documents/Rose%20Sheet/2019/09/9%20Sept%202019%20Valisure%20Ranitidine%20Petition.pdf.

[8] Valisure Petition, at 6.

greater than the FDA's daily permissible intake levels of 96 ng of NDMA per day.[9]

8. This level of NDMA is exacerbated by the inherent instability of the ranitidine molecule itself. The ranitidine molecule contains both a nitrite and a dimethylamine ("DMA") group which are well known to combine to form NDMA.[10] Thus, ranitidine produces NDMA by "react[ing] with itself,"[11] which means that every dosage and form of ranitidine, including Zantac, exposes users to NDMA.[12]

9. Moreover, studies have shown that conditions within the body contribute to trigger the formation of NDMA. Specifically, gastric fluid mechanisms and enzymatic mechanism via dimethylarginine dimethylaminohydrolase ("DDAH") for the liberation of ranitidine's DMA group which can occur in other tissues and organs separate from the stomach facilitating the formation of NDMA.[13] When Valisure tested Zantac "in conditions simulating the human stomach," the quantity of NDMA detected was as high as 304,500 ng per tablet -- 3,171 times more than the amount that can be safely ingested daily.[14]

10. Even though Valisure filed its Citizen Petition in June 2019, the FDA did not act until September 13, 2019, when it issued a statement announcing the presence of NDMA in

[9] *FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)*, FDA (last updated Aug. 28, 2019) (setting "interim limits for NDMA" and other nitrosamines at 96 ng/day for angiotensin II receptor blockers).

[10] Valisure Petition, at 1.

[11] *Id.*., at 2

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[12] *Id*., at 1.

[13] Valisure Petition, at 6-8; Teng Zeng & William A. Mitch, *Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine*, 37(6) CARCINOGENESIS 625 (Mar. 18, 2016).

[14] *Id.*

ranitidine medications, including Zantac.[15] The FDA's notice states that "NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests." Since then, the FDA's own testing "has found unacceptable levels of NDMA in samples of ranitidine."[16] Nevertheless, the FDA did not institute a recall or force manufacturers, distributors or retailers to withdraw the product from the market.

11. Several pharmaceutical manufacturers have issued recalls or halted the sale of their ranitidine medications. Pharmacies such as Walmart, Walgreens, Rite Aid, and CVS have also ceased or suspended selling ranitidine medications. Sanofi has also agreed to an informal voluntary recall of Zantac "[d]ue to inconsistencies in preliminary test results of the active ingredient used in Zantac products."[17] Sanofi, however, is yet to issue a formal recall of Zantac. In fact, Sanofi has continued to tout the safety of Zantac on Zantac's website, stating: "[t]he longstanding science supports the safety of Zantac, which has been available over-the-counter for over two decades."[18]

THE MARKETING CAMPAIGN

12. Boehringer and Sanofi have always marketed Zantac as a safe and effective product, and Sanofi has continued to do so despite the recent recalls of ranitidine medications.

13. On Zantac's website, Sanofi currently continues to proclaim Zantac is "[c]linically

[15] Statement, Food & Drug Admin., Statement Alerting Patients and Health Care Professionals of NDMA Found in Samples of Ranitidine (Sept. 13, 2019), https://www.fda.gov/news-events/press-announcements/statement-alerting-patients-and-health-care-professionals-ndma-found-samples-ranitidine.

[16] Food & Drug Admin., 10/2/19: UPDATE – FDA Provides Update on Testing of Ranitidine for NDMA Impurities (Oct. 2, 2019), https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine.

[17] https://www.zantacotc.com/

[18] ZANTAC STATEMENT, https://www.zantacotc.com/zantac-statement.html

proven to relieve heartburn in as little as 30 minutes."[19] Sanofi also assures consumers it is safe to "take up to two (2) Zantac tablets a day."[20]

14. In accordance with Sanofi's assurance of safety, "[t]he typical recommended dose of ranitidine for therapy of peptic ulcer disease in adults is 150 mg twice daily or 300 mg once nightly for 4 to 8 weeks, and maintenance doses of 150 mg once daily."[21] Moreover, chronic use of the drug is common "for therapy of heartburn and indigestion."[22]

15. Thus, based upon the results of Valisure's FDA approved testing, a typical consumer who is taking Zantac over the course of eight weeks to treat peptic ulcer disease is exposed to more than 280,000,000 ng (or 0.28 grams) of NDMA. Moreover, a consumer who takes a 150 mg maintenance dose of Zantac once daily is exposed to 889,000,000 ng (0.889 grams) of NDMA over the course of a year. This is disconcerting as the FDA's permissible intake limit of NDMA is 96 ng per day, which translates to just 0.000034 grams per year for consumers who take a 150 mg maintenance dose daily.

16. Sanofi has continued to tout the safety of Zantac on the product's website, stating: "it's important to note that at this time the FDA is not calling for individuals to stop taking Zantac®, nor has the FDA requested that Sanofi stop shipping to retailers. The longstanding science supports the safety of Zantac, which has been available over-the-counter for over two decades."

ZANTAC CONTAINS DANGEROUS LEVELS OF NDMA

17. Contrary to the above assertions, Zantac contains dangerously high levels of

[19] MAXIMUM STRENGTH ZANTAC 150, https://www.zantacotc.com/zantac-maximum-strength.html#learn-more

[20] *Id.*

[21] Drug Record: Ranitidine, NATIONAL INSTITUTES OF HEALTH (updated July 1, 2019), https://livertox.nih.gov/Ranitidine.htm.

[22] *Id.*

NDMA that would not be present if the medication were properly synthesized.

18. Unlike the FDA, countries around the globe have recalled or suspended the sale of ranitidine medications such as Zantac due to the dangerous levels of NDMA. For example, the Medicines and Healthcare Regulatory Agency of the United Kingdom has issued an alert regarding Zantac, noting recalls issued by companies are "a precautionary measure due to possible contamination of the active substance in Zantac, ranitidine, with an impurity called NDMA."[23] "The MHRA has asked manufacturers to quarantine all ranitidine products which may contain the active pharmaceutical ingredient that is potentially affected by this issue."[24] Similarly, the Health Products Regulatory Authority of Ireland, in issuing a recall of Zantac, has stated, "The reason for the recall is that a nitrosamine impurity has been identified in ranitidine active substance batches manufactured at a manufacturing site in India."[25]

19. Moreover, Germany, Switzerland, and Austria all have initiated recalls of ranitidine-based drugs,[26] and Finland has withdrawn drugs containing ranitidine from its pharmacies.[27] The Italian Drug Agency also has recalled certain ranitidine-based drugs,[28] while

[23] Medicine and Healthcare Regulatory Agency, Zantac – MHRA Drug Alert Issued as GlaxoSmithKline Recalls all Unexpired Stock (Oct. 8, 2019), https://www.gov.uk/government/news/zantac-mhra-drug-alert-issued-as-glaxosmithkline-recalls-all-unexpired-stock.

[24] *Id*.

[25] Health Products Regulatory Authority, Precautionary Pharmacy and Retail Level Recall of Several Batches of a Number of Ranitidine Medicines in Ireland (Sept. 23, 2019), https://www.hpra.ie/homepage/medicines/safety-notices/item?t=/precautionary-pharmacy-and-retail-level-recall-of-several-batches-of-a-number-of-ranitidine-medicines-in-ireland&id=d26b0c26-9782-6eee-9b55-ff00008c97d0.

[26] Tom Gallen, Ranitidine Recalls Begin In Europe As Regulators Take Action, PHARMA INTELLIGENCE (Sept. 18, 2019), https://hbw.pharmaintelligence.informa.com/RS149219/ Ranitidine-Recalls-Begin-In-Europe-As-Regulators-Take-Action.

[27]Pharmacies pull heartburn meds over contamination concerns, UUTISET (Sept. 19, 2019), https://yle.fi/uutiset/osasto/news/pharmacies_pull_heartburn_meds_over_contamination_ concerns/10977530.

[28] PB Jayakumar, Anti-acidity drug ranitidine gives heartburn to industry and public, BUSINESS TODAY (Sept. 24, 2019), https://www.businesstoday.in/sectors/pharma/anti-acidity-drug- ranitidine-gives-heartburn-to-industry-and-public/story/380916.html.

Singapore has suspended the sale and supply of several brands of ranitidine.[29] Likewise, Qatar's Ministry of Public Health "has withdrawn samples of ranitidine, including the one commercially known as Zantac, from public and private pharmacies" and has "recommend[ed] patients who use these drugs to review and consult their doctor, and those who use them without a prescription should use other alternatives."[30]

20. The FDA has established a "permissible daily intake limit for…NDMA of 96 [nanograms]."[31] But Zantac has an NDMA content of between 2.5-3.3 million nanograms *per tablet*, according to testing by Valisure, an FDA-registered online pharmacy:[32]

150 mg Tablets or equivalent	Lot #	NDMA per tablet (ng)
Reference Powder	125619	2,472,531
Zantac, Brand OTC	18M498M	2,511,469
Zantac (mint), Brand OTC	18H546	2,834,798
Wal-Zan, Walgreens	79L800819A	2,444,046
Wal-Zan (mint), Walgreens	8ME2640	2,635,006
Ranitidine, CVS	9BE2773	2,520,311
Zantac (mint), CVS	9AE2864	3,267,968
Ranitidine, Equate	9BE2772	2,479,872
Ranitidine (mint), Equate	8ME2642	2,805,259
Ranitidine, Strides	77024060A	2,951,649

21. Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA

[29] Singapore halts sales of some antacids over stomach cancer concerns, SOUTH CHINA MORNING POST (Sept. 16, 2019), https://www.scmp.com/news/asia/southeast-asia/article/3027521/ singapore-halts-sales-some-antacids-over-stomach-cancer.

[30] Health ministry recalls Zantac as a precautionary measure, QATAR TRIBUNE (Sept. 16, 2019), http://www.qatar-tribune.com/news-details/id/172460.

[31] Valisure Petition, at 6.

[32] *Id*.

considers acceptable."[33]

PLAINTIFF WAS HARMED BY PURCHASING AND CONSUMING DEFECTIVE ZANTAC

22. Plaintiff and the Class were injured by the full purchase price of their Zantac medications. These medications are worthless, as they contain harmful levels of NDMA. As the medications expose users to NDMA well above the legal limit, the medications are not fit for human consumption. Plaintiff is further entitled to statutory damages, damages for the injury sustained in consuming high levels of acutely-toxic NDMA, and for damages related to Defendants' conduct.

23. Plaintiff brings this action on behalf of the Class for equitable relief and to recover damages and restitution for: (i) breach of express warranty, (ii) breach of the implied warranty of merchantability, (iii) violation of New York Gen. Bus. Law § 349, (iv) violation of New York Gen. Bus. Law § 350, (v) unjust enrichment, (vi) fraudulent concealment, (vii) and fraud.

PARTIES

24. Plaintiff Robert Froehlich is a citizen of New York who resides in Orange County, New York. During all relevant time periods, Mr. Froehlich purchased and consumed Zantac manufactured by Defendants Boehringer and Sanofi, distributed by Defendant Chattem, and sold by Defendant Walmart. Mr. Froehlich originally learned about the Zantac defect when he viewed articles regarding the suspension of the sale of Zantac, including an article on Facebook from CNN, entitled "Walmart, CVS, Walgreens Pull Zantac and Similar Heartburn Drugs because of Cancer Worries." Further investigation revealed that Mr. Froehlich has been using the defective Zantac manufactured by Boehringer and Sanofi and distributed by Chattem since at least 2016. When

[33] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn- pills-2019-10-08/.

purchasing Zantac from Defendants, Mr. Froehlich reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly manufactured, free from defects, and safe for their intended use. Mr. Froehlich relied on these representations and warranties in deciding to purchase Zantac from Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased Zantac from Defendants if he had known that they were not, in fact, properly manufactured and free from defects. Mr. Froehlich also understood that in making the sales, Walmart was acting with the knowledge and approval of Boehringer and Sanofi and/or as the agents of Boehringer and Sanofi. Mr. Froehlich also understood that each purchase involved a direct transaction between himself and Boehringer and/or Sanofi because his medication came with packaging and other materials prepared by Boehringer and/or Sanofi, including representations and warranties that his medications were properly manufactured and free from defects.

25. Defendant Sanofi-Aventis U.S. LLC is a corporation incorporated under the laws of Delaware with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC is a wholly owned subsidiary of French company Sanofi S.A. Sanofi conducts substantial business in the United States, and specifically in the State of New York. Sanofi has been engaged in the manufacturing, distribution, and sale of defective Zantac in the United States, including in the State of New York.

26. Defendant Sanofi US Services Inc. is a corporation organized under the laws of the laws of Delaware with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi. Sanofi conducts substantial business in the United States, and specifically in the State of New York. Sanofi has

been engaged in the manufacturing, distribution, and sale of defective Zantac in the United States, including in the State of New York.

27. Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. are collectively referred to as Sanofi.

28. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer') is a corporation organized under the laws of Delaware with a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877 and is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned the U.S. rights to over-the-counter Zantac from about October 2006 to January 2017, and manufactured and distributed the drug in the United States during that period.

29. Defendant Chattem, Inc. ("Chattem") is a corporation incorporated under the laws of Tennessee with its principal place of business at 1715 West 38th Street, Chattanooga, Tennessee 37409. Chattem manages the supply and distribution of Zantac in the United States on behalf of Sanofi. Chattem is a wholly owned subsidiary of French company Sanofi S.A.

30. There exists, and at all times herein existed, a unity of ownership between Sanofi, Chattem, and their agents such that any individuality or separateness between them has ceased and each of them is the alter ego of the other. Upon information and belief, Sanofi communicates with Chattem concerning virtually all aspects of the Zantac it distributes in the United States. At all relevant times, Chattem acted as an authorized agent, representative, servant, employee and/or alter ego of Sanofi while performing activities including but not limited to advertising, warranties, dissemination of information, and distribution of Zantac medications in the United States and in the State of New York.

31. Defendant Walmart Inc. ("Walmart") is a corporation organized under the laws of

the State of Delaware and maintains its principal place of business at 702 SW 8th Street, Bentonville, Arkansas 72716-8611. Among other services, Walmart provides pharmacy services. Defendant Walmart conducts substantial business throughout the United States, and specifically in the State of New York. Mr. Froehlich purchased Zantac from a Walmart store in Orange County, New York.

JURISDICTION AND VENUE

32. This Court also has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2), as amended by the Class Action Fairness Act of 2005 ("CAFA") because (a) the matter in controversy, exclusive of interest and costs, exceeds the sum of $5,000,000.00, and (b) is a class action in which Plaintiff and two-thirds of the proposed Class Members are from a different state than Defendants.

33. Personal jurisdiction is derived from the fact that Defendants systematically and continuously conduct business within the state of New York.

34. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, and because Defendants (a) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of Zantac in this District; and (b) conduct substantial business in this District.

CLASS ALLEGATIONS

35. Pursuant to Federal Rule of Civil Procedure 23, Plaintiff seeks to represent a class defined as all persons in the United States who purchased Zantac (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts,

representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

36. Pursuant to Federal Rule of Civil Procedure 23, Plaintiff also seeks to represent a subclass of all Class members who purchased Zantac in New York (the "New York Subclass").

37. The classes described in this Complaint will be jointly referred to as "Class," and proposed members in the classes will be jointly referred to as "Class Members."

38. Plaintiff reserves the right to amend or modify Class definitions with greater specificity or further division into subclasses or limitation to particular issues as discovery and the orders of this Court warrant.

39. The Court can define the Class and create additional subclasses as may be necessary or desirable to adjudicate common issues and claims of the Class Members if, based on discovery of additional facts, the need arises

40. The members of the Class are so numerous that their individual joinder herein is impracticable. The precise number of Class Members and their identities are unknown to Plaintiff at this time but will be determined through discovery. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class. Accordingly, joinder is impracticable.

41. There are numerous questions of law and fact common to the Class which predominate over any individual actions or issues, including, but not limited to:

(a) Whether the Zantac manufactured, distributed, and sold by Defendants contain excessive levels of NDMA, thereby breaching the express and implied warranties made

by Defendants and making Zantac unfit for human consumption and therefore unfit for its intended purpose;

(b) Whether Defendants knew or should have known that Zantac contained excess levels of NDMA prior to selling the medication, thereby constituting fraud and/or fraudulent concealment;

(c) Whether Defendants are liable to Plaintiff and the Class and New York Subclass for unjust enrichment;

(d) Whether Defendants are liable to Plaintiff and the Class and New York Subclass for fraudulent concealment;

(e) Whether Defendants are liable to Plaintiff and the New York Subclass for violations of the New York consumer-protection law;

(f) Whether Defendants are liable to Plaintiff and the Class and New York Subclass for breaches of express and implied warranties;

(g) Whether Plaintiff and the Class and New York Subclass have sustained monetary loss and the proper measure of that loss;

(h) Whether Plaintiff and the Class and New York Subclass are entitled to declaratory and injunctive relief;

(i) Whether Plaintiff and the Class and New York Subclass are entitled to restitution and disgorgement from Defendants; and

(j) Whether the marketing, advertising, packaging, labeling, and other promotional materials for Zantac are misleading and/or deceptive.

42. Plaintiff's claims are typical of the claims of the other members of the Class and New York Subclass in that Defendants mass marketed and sold defective Zantac to consumers

throughout the United States. This defect was present in all of the Zantac manufactured, distributed, and sold by Defendants. Therefore, Defendants breached their express and implied warranties to Plaintiff and Class and New York Subclass members by manufacturing, distributing, and selling the defective Zantac. Plaintiff's claims are typical in that they were uniformly harmed in purchasing and consuming the defective Zantac. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class and New York Subclass. Further, there are no defenses available to Defendants that are unique to Plaintiff.

43. Plaintiff is an adequate representatives of the Class and New York Subclass because his interests do not conflict with the interests of Class Members he seeks to represent, and has retained counsels competent and experienced in prosecuting class actions, and intends to prosecute this action vigorously.

44. Plaintiff will fairly and adequately represent and protect the interests of Class Members, and common issues predominate

45. Notice of this class action can be provided to Class Members by techniques and forms similar to those customarily used in other class actions, such as by published notice, Internet notice, first-class mail or a combination thereof, or other means deemed suitable for this Class.

46. Class certification is appropriate because Defendants have acted, or refused to act, on grounds generally applicable to the Class, making class-wide relief appropriate.

47. In addition, the class mechanism is superior to other available means for the fair and efficient adjudication of the claims of Plaintiff and Class Members. Each individual Class Member may lack the resources to undergo the burden and expense of individual prosecution of the complex and extensive litigation necessary to establish Defendants' liability. Individualized

litigation increases the delay and expense to all parties and multiplies the burden on the judicial system presented by the complex legal and factual issues of this case. Individualized litigation also presents a potential for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer management difficulties and provides the benefits of single adjudication, economy of scale, and comprehensive supervision by a single court on the issue of Defendants' liability. Class treatment of the liability issues will ensure that all claims and claimants are before this Court for consistent adjudication of the liability issues.

COUNT I
BREACH OF EXPRESS WARRANTY
(On Behalf Of The Class And New York Subclass)

48. Plaintiff and Class Members re-allege and incorporate by reference each and every allegation set forth above, and further allege as follows:

49. Plaintiff brings Count I individually and on behalf of the members of the proposed Class and the New York Subclass against Defendants.

50. Plaintiff, and each member of the Class and New York Subclass, formed a contract with Defendants at the time Plaintiff and the other Class and New York Subclass members purchased the defective Zantac. The terms of the contract include the promises and affirmations of fact made by Defendants on Zantac's packaging and through marketing and advertising, including that the product would contain only what was stated on the label, and not harmful impurities such as NDMA. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the Class and New York Subclass and Defendants.

51. Plaintiff relied on the express warranty that his Zantac was safe and would not contain unsafe levels of NDMA. This express warranty further formed the basis of the bargain

and is part of the standardized contract between Plaintiff and the members of the Class and New York Subclass and Defendants.

52. Defendants purport, through their advertising, labeling, marketing and packaging, to create an express warranty that the medication would contain only the ingredients stated on the label, and not harmful impurities/carcinogens such as NDMA.

53. Plaintiff and the Class and New York Subclass performed all conditions precedent to Defendants' liability under this contract when they purchased the defective medication.

54. Defendants breached express warranties about the defective Zantac and its qualities because Defendants' statements about the defective Zantac were false and the defective Zantac does not conform to Defendants' affirmations and promises described above.

55. Plaintiff and each of the members of the Class and New York Subclass would not have purchased the defective Zantac had they known the true nature of the defective Zantac's composition, specifically that Zantac contained excess levels of carcinogenic NDMA.

56. As a result of Defendants' breaches of express warranty, Plaintiff and each of the members of the Class and New York Subclass have been damaged in the amount of the purchase price of Zantac and any consequential damages resulting from the purchases.

57. Prior to filing this action, Defendants were served with a pre-suit notice letter ("Pre-Suit Notice") that complied in all respects with U.C.C. §§ 2-313, 2-607. Plaintiff's counsel sent Defendants Pre-Suit Notice advising them that they breached an express warranty and demanded that they cease and desist from such breaches and make full restitution by refunding the monies received therefrom.

COUNT II
BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY
(On Behalf Of The Class And New York Subclass)

58. Plaintiff and Class Members re-allege and incorporate by reference each and every allegation set forth above, and further allege as follows:

59. Plaintiff brings Count II individually and on behalf of the members of the proposed Class and the New York Subclass against Defendants.

60. Defendants, as the designers, manufacturers, marketers, distributors, and/or sellers, impliedly warranted that Zantac: (i) would not contain excess levels of carcinogenic NDMA, and (ii) is generally recognized as safe for human consumption.

61. Defendants breached the warranty implied in the contract for the sale of the defective Zantac because it could not pass without objection in the trade under the contract description, the Zantac was not of fair or average quality within the description, and the Zantac was unfit for its intended and ordinary purpose because the Zantac manufactured, distributed, and sold by Defendants was defective in that it contained excessive levels of carcinogenic NDMA, and as such is not generally recognized as safe for human consumption. As a result, Plaintiff and Class and New York Subclass members did not receive the goods as impliedly warranted by Defendants to be merchantable.

62. Plaintiff and Class and New York Subclass members purchased Zantac in reliance upon Defendants' skill and judgment and the implied warranties of fitness for the purpose.

63. The Zantac was defective when it left the exclusive control of Defendants and was not altered by Plaintiff or Class and New York Subclass members.

64. Defendants knew that the Zantac would be purchased and used without additional testing by Plaintiff and Class and New York Subclass members.

65. The defective Zantac was defectively manufactured and unfit for its intended purpose, and Plaintiff and Class and New York Subclass members did not receive the goods as warranted.

66. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class and New York Subclass members have been injured and harmed because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained excessive levels of carcinogenic NDMA, and is not generally recognized as safe for human consumption; and (b) Zantac does not have the characteristics, ingredients, uses, or benefits as promised by Defendants.

COUNT III
VIOLATION OF NEW YORK GEN. BUS. LAW § § 349
(On Behalf Of The New York Subclass)

67. Plaintiff and Class Members re-allege and incorporate by reference each and every allegation set forth above, and further allege as follows:

68. Plaintiff brings Count III individually and on behalf of the members of the proposed Class and the New York Subclass against Defendants.

69. Section § 349 of the New York Gen. Bus. Law prohibits deceptive acts or practices in the conduct of any business, trade, or commerce.

70. Defendants conduct business and trade throughout the State of New York within the meaning of Section § 349 of the New York Gen. Bus. Law.

71. Plaintiff and members of the New York Subclass are consumers who purchased products from Defendants for personal use.

72. By the acts and conduct alleged herein, Defendants have engaged in deceptive, unfair, and misleading acts and practices, which include, without limitation, misrepresenting that

Zantac (i) would not contain excessive levels of carcinogenic NDMA, and (ii) is generally recognized as safe for human consumption.

73. The foregoing deceptive acts and practices were directed at consumers.

74. The foregoing deceptive acts and practices are misleading in a material way because they fundamentally misrepresent the characteristics and quality of Zantac to induce consumers to purchase the same.

75. By reason of this conduct, Defendants engaged in deceptive conduct in violation of Section § 349 of the New York Gen. Bus. Law.

76. Defendants' actions are the direct, foreseeable, and proximate cause of the damages that Plaintiff and members of the New York Subclass have sustained from having paid for and used Defendants' products.

77. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained excessive levels of carcinogenic NDMA; and (b) Zantac does not have the characteristics, uses, benefits, or qualities as promised.

78. On behalf of himself and other members of the New York Subclass, Plaintiff seeks to recover his actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT IV
VIOLATION OF NEW YORK GEN. BUS. LAW § § 350
(On Behalf Of The New York Subclass)

79. Plaintiff and Class Members re-allege and incorporate by reference each and every allegation set forth above, and further allege as follows:

80. Plaintiff brings Count IV individually and on behalf of the members of the proposed

Class and the New York Subclass against Defendants.

81. Section § 350 of the New York Gen. Bus. Law prohibits false advertising in the conduct of any business, trade, or commerce.

82. Section § 350 of the New York Gen. Bus. Law defines false advertising as "advertising, including labeling, of a commodity … if such advertising is misleading in a material respect."

83. Defendants have engaged in consumer-oriented conduct that is deceptive or misleading in a material way which constitutes false advertising in violation of Section § 350 of the New York Gen. Bus. Law.

84. Defendants' false, misleading, and deceptive statements and representations of fact were and are directed towards consumers.

85. Defendants' false, misleading, and deceptive statements and representations of fact were and are likely to mislead a reasonable consumer acting reasonably under the circumstances.

86. Defendants' false, misleading, and deceptive statements and representations of fact have resulted in consumer injury or harm to the public interest.

87. As a result of Defendants' false, misleading, and deceptive statements and representations of fact, Plaintiff and the New York Subclass have suffered and continue to suffer economic injury.

88. As a result of Defendants' violations, Plaintiff and members of the New York Subclass have suffered damages due to said violations because: (a) they would not have purchased Zantac on the same terms if they knew that Zantac contained excess levels of carcinogenic NDMA and is not safe for human consumption; and (b) Zantac does not have the characteristics, uses, benefits, or qualities as promised.

89. On behalf of himself and other members of the New York Subclass, Plaintiff seeks to recover his actual damages or five hundred dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT V
UNJUST ENRICHMENT
(On Behalf Of The Class And New York Subclass)

90. Plaintiff and Class Members re-allege and incorporate by reference each and every allegation set forth above, and further allege as follows:

91. Plaintiff brings Count V individually and on behalf of the members of the proposed Class and the New York Subclass against Defendants.

92. Plaintiff and the Class and New York Subclass conferred non-gratuitous benefits on Defendants in the form of monies paid to purchase Defendants' defective Zantac.

93. Defendants voluntarily accepted or retained such non-gratuitous benefits with full knowledge that Plaintiff and Class Members were not receiving products of the nature and quality that Defendants represented.

94. By virtue of the unlawful conduct described herein, it would be unjust and inequitable for Defendants to retain the non-gratuitous benefits conferred. Therefore, Plaintiff and Class Members are entitled to, and hereby seek, disgorgement and restitution of wrongful profits, revenue, and benefits conferred upon Defendants in a manner established by the Court

COUNT VI
FRAUDULENT CONCEALMENT
(On Behalf Of The Class and New York Subclass)

95. Plaintiff and Class Members re-allege and incorporate by reference each and every allegation set forth above, and further allege as follows:

96. Plaintiff brings Count VI individually and on behalf of the members of the proposed

Class and the New York Subclass against Defendants.

97. Defendants had a duty to disclose material facts to Plaintiff and the Class and New York Subclass given their relationship as contracting parties and intended users of Zantac. Defendants also had a duty to disclose material facts to Plaintiff and the Class and New York Subclass, namely that they were in fact manufacturing, distributing, and selling Zantac with excess levels of NDMA unfit for human consumption, because Defendants had superior knowledge such that the transactions without the disclosure were rendered inherently unfair.

98. Defendants possessed knowledge of these material facts. In 2003, it was "proposed that elevated levels of NDMA in drinking water…may be associated with the drug ranitidine."[34] Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[35] During that time, Plaintiff and Class and New York Subclass members were using Zantac without knowing it contained excessive levels of carcinogenic NDMA.

99. Defendants failed to discharge their duty to disclose these materials facts.

100. In so failing to disclose these material facts to Plaintiff and the Class and New York Subclass, Defendants intended to hide from Plaintiff and the Class and New York Subclass that they were purchasing and consuming Zantac with harmful and excessive levels of carcinogenic NDMA that were unfit for human use, and thus acted with scienter and/or an intent to defraud.

101. Plaintiff and the Class and New York Subclass reasonably relied on Defendants' failure to disclose insofar as they would not have purchased the defective Zantac manufactured,

[34] VALISURE PETITION at 4-5.

[35] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/.

distributed, and sold by Defendants had they known it contained excessive levels of carcinogenic NDMA.

102. As a direct and proximate cause of Defendants' fraudulent concealment, Plaintiff and the Class and New York Subclass suffered damages in the amount of monies paid for the defective Zantac.

103. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

COUNT VII
FRAUD
(On Behalf Of The Class and New York Subclass)

104. Plaintiff and Class Members re-allege and incorporate by reference each and every allegation set forth above, and further allege as follows:

105. Plaintiff brings Count VII individually and on behalf of the members of the proposed Class and the New York Subclass against Defendants.

106. As discussed above, Defendants provided Plaintiff and Class and New York Subclass members with materially false or misleading information about the Zantac manufactured, distributed, and sold by Defendants. Specifically, Defendants have marketed Zantac as safe for human consumption. As indicated above, however, these representations are false and misleading as Defendants' Zantac medications contained excess levels of carcinogenic NDMA.

107. The misrepresentations and omissions of material fact made by Defendants, upon which Plaintiff and Class and New York Subclass members reasonably and justifiably relied, were intended to induce and actually induced Plaintiff and Class and New York Subclass members to purchase defective Zantac.

108. Defendants knew that Zantac was contaminated with this harmful impurity, but

continued to manufacture it nonetheless. In 2003, it was "proposed that elevated levels of NDMA in drinking water … may be associated with the drug ranitidine."[36] Furthermore, a 2016 study by Stanford University found that individuals who took Zantac had "NDMA levels [in their urine] more than 400 times greater than what the FDA considers acceptable."[37] During that time, Plaintiff and Class and New York Subclass members were using the medication without knowing it contained excessive levels of carcinogenic NDMA.

109. The fraudulent actions of Defendants caused damage to Plaintiff and Class and New York Subclass members, who are entitled to damages and other legal and equitable relief as a result.

110. As a result of Defendants' willful and malicious conduct, punitive damages are warranted.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, requests that the Court enter an order or judgment against Defendants including the following:

A. An order certifying that this action is properly brought and may be maintained as a class action;

B. An order appointing Plaintiff as class representative of a Nationwide Class, as class representatives of the New York Subclass, and his undersigned counsel as lead counsel for the Class;

C. An order requiring Defendants to bear the costs of Class notice;

[36] VALISURE PETITION at 4-5.

[37] Jonathan Lapook, *Potentially Dangerous Chemical Found in Popular Heartburn Pill Zantac*, CBS NEWS, Oct. 8, 2019, https://www.cbsnews.com/news/zantac-ndma-levels-potentially-dangerous-chemical-zantac-ranitidine-heartburn-pills-2019-10-08/.

D. An order declaring the Defendants' conduct violates the statutes referenced herein;

E. Restitution in such amount that Plaintiff and Class Members paid to purchase Defendants defective Zantac;

F. Actual damages, compensatory damages, punitive or treble damages, and such other relief as provided by the statutes cited herein;

G. Statutory damages allowable under New York Gen. Bus. Law §§ 349 and 350-e

H. Other appropriate injunctive relief;

I. An order awarding Plaintiff his costs of suit, including reasonable attorneys' fees and pre- and post-judgment interest on such monetary relief;

J. An order requiring an accounting for, and imposition of, a constructive trust upon all monies Defendants received as a result of the misleading, fraudulent, and unlawful conduct alleged herein.

K. Such other relief to which Plaintiff and Class Members may be entitled to at law or in equity.

JURY DEMAND

Plaintiff hereby demands a trial by jury of any and all issues in this action so triable.

Dated: December 19, 2019

VOZZOLO LLC

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